UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

JANET ADAMS, ET AL.	§	
	§	
v.	§	CIVIL NO. 4:19-CV-870-SDJ
	§	
MEDTRONIC, INC., ET AL.	§	

MEMORANDUM ADOPTING REPORT AND RECOMMENDATION OF UNITED STATES MAGISTRATE JUDGE

Came on for consideration the report of the United States Magistrate Judge in this action, this matter having been heretofore referred to the Magistrate Judge pursuant to 28 U.S.C. § 636. On March 3, 2022, the Magistrate Judge entered a Report and Recommendation ("Report"). (Dkt. #66). In the Report, the Magistrate Judge recommended that Defendants Medtronic, Inc., Covidien LP, Covidien Sales LLC, and Covidien Holding, Inc.'s (collectively, "Covidien") Motion to Dismiss Count I of Plaintiffs' Second Amended Complaint, (Dkt. #26), be granted in part and denied in part. Plaintiffs Janet Adams and Randy Adams filed Objections, (Dkt. #68), to which Covidien filed a response, (Dkt. #73).

The Court has conducted a de novo review of the Objections and the portions of the Report to which the Adamses specifically object, and the Court is of the opinion that the findings and conclusions of the Magistrate Judge are correct and that the Objections are without merit as to the ultimate findings of the Magistrate Judge. The Court hereby adopts the findings and conclusions of the Magistrate Judge as the findings and conclusions of the Court.

I. BACKGROUND

On December 19, 2017, Janet Adams was admitted to Baylor Medical Center for a standard procedure known as an "ileostomy takedown." Janet Adams's surgeon, Dr. Laurie Novosad, performed part of the procedure using an end-to-end anastomosis stapler ("EEA Stapler"). The Adamses allege that despite Dr. Novosad properly operating the device, the EEA Stapler "misfired and cut [Janet Adams's] intestines, without the staples engaging." (Dkt. #25 ¶ 25). As a result of the misfire, Janet Adams underwent additional surgical procedures, required extended hospitalization, had portions of her bowels removed, suffered massive scarring and permanent bowel damage, and incurred additional medical bills. (Dkt. #25 ¶¶ 27, 29, 30–32).

Subsequently, the Adamses initiated this lawsuit against Covidien, alleging that Covidien designed, manufactured, and sold the allegedly defective EEA Stapler. The Adamses contend that powered surgical staplers are a safer and economically feasible alternative to manually fired staplers like the EEA Stapler.

The Adamses initiated this lawsuit in state court in Collin County, Texas. Covidien removed the action to this Court and moved to dismiss the Adamses' original complaint. The Adamses filed their First Amended Complaint as a matter of course, asserting six causes of action: (1) defective design; (2) manufacturing defect; (3) failure to warn; (4) breach of implied warranty; (5) breach of express warranty; and (6) loss of consortium. Covidien moved to dismiss, and the Court dismissed each claim without prejudice. (Dkt. #24). The Adamses filed the Second Amended Complaint, asserting only three causes of action: (1) defective design; (2) failure to

warn; and (3) loss of consortium. The Adamses seek exemplary damages in connection with their claims. (Dkt. #25 ¶ 86). Covidien moved to dismiss the Adamses' design defect claim and to strike the Adamses' request for exemplary damages.

In light of the pleadings, arguments, and applicable authorities, the Report recommended the following: (1) the motion to dismiss should be granted as to the design defect claim, as the Adamses failed to state a claim; and (2) the motion to dismiss should be denied as to striking the Adamses' request for exemplary damages.

II. DISCUSSION

The Adamses object to the Magistrate Judge's conclusion on the design defect claim and argue that they sufficiently pleaded the existence of a safer alternative design. In the alternative, the Adamses seek leave to amend.

A. Safer Alternative Design

i. Motion to dismiss

Under Texas law, a strict-liability design defect claim requires a plaintiff to plead: "(1) the product was defectively designed so as to render it unreasonably dangerous; (2) a safer alternative design existed; and (3) the defect was a producing cause of the injury for which the plaintiff seeks recovery." *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 765 (5th Cir. 2018) (quotation omitted). Design defect claims sounding in negligence also require the existence of a safer alternative design. *See Flynn v. Am. Honda Motor Co.*, No. 4:11-CV-3908, 2015 WL 75270, at *5 (S.D. Tex. Jan. 6, 2015), *aff'd*, 653 F.App'x 820 (5th Cir. 2016). The Magistrate Judge found that the Adamses did not adequately allege that a safer alternative design existed.

"A safer alternative design is one that would have prevented or significantly reduced the risk of injury, would not substantially impair the product's utility, and was economically and technologically feasible at the time." *Genie Indus. v. Matak*, 462 S.W.3d 1, 7 (Tex. 2015) (citation omitted). A plaintiff cannot establish the existence of a safer alternative design by pointing to an entirely different product. *Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760, 770 (Tex. App.—Houston [14th Dist.] 2009, no pet.).

The Adamses pleaded that a powered stapler is a safer alternative to the manual stapler used during Janet Adams's surgery. But the Magistrate Judge found this pleading inadequate because by proposing powered staplers as an alternative, the Adamses "proposed a substantially different product." (Dkt. #66 at 18). The Adamses object that this issue of fact should be left for the jury because "reasonable minds . . . can differ as to whether a surgical stapler device, powered or unpowered, is the same device." (Dkt. #68 at 3).

In support of their objection, the Adamses raise two novel arguments.[1] First, they contend that because the EEA Stapler and another Covidien product, the EEA circular Tri-Stapler, are listed as "predicate devices" in device history safety reports, it is plausible that powered and unpowered surgical stapler devices are the same. This argument misses the mark. Quoting Covidien's Section 501(K) premarket notification of intent to market the Tri-Stapler, the Adamses state: "The EEA circular

[1] Because the Court's conclusion is unchanged even if it takes into account the Adamses' new arguments, the Court declines to decide whether it should exercise its discretion to ignore arguments that were not adequately presented to the Magistrate Judge.

stapler with Tri-Staple technology has the same intended use as the identified predicate device. They are similar in fundamental scientific technology in that they are all . . . ***manual*** surgical instruments . . . .” (Dkt. #68 at 3 n.5 (emphasis added)). At most, this argument could support an assertion that the EEA Stapler and the Tri-Stapler—two manual staplers—are sufficiently similar. But this argument has no bearing on the Magistrate Judge’s finding that powered (i.e., non-manual) and manual (i.e., non-powered) staplers are substantially different products.

Second, the Adamses argue that “[o]nly where the Plaintiff fails to offer evidence of an element does a design-defect claim fail as a matter of law.” (Dkt. #68 at 3 (citing *Smith v. Aqua-Flo, Inc.*, 23 S.W.3d 473, 477 (Tex. App.—Houston [1st Dist.] 2000, pet. denied))). The legal standard recited by the *Smith* court was the standard for a directed verdict. 23 S.W.3d at 476. At the motion to dismiss stage, a plaintiff must “allege sufficient facts to support the plausibility of” a safer alternative design. *Rodriguez v. Gilead Scis., Inc.*, No. 2:14-CV-324, 2015 WL 236621, at *3 (S.D. Tex. Jan. 16, 2015). The Magistrate Judge correctly found that the Adamses did not do so here because their pleadings rely on the existence of an entirely different product, not a safer alternative design.

For the foregoing reasons, the Court overrules the Adamses’ objection.

ii. Request for leave to amend

In the alternative, the Adamses request leave to amend because subsequent investigation allegedly has revealed “a simple, inexpensive, and available fix for the [EEA Stapler] which would have prevented [Janet Adams’s] injury.” (Dkt. #68 at 4).

According to the Adamses, if an O-ring is inserted in the EEA Stapler's upper platform, the device could accommodate tissue variabilities. The Adamses contend that this design change would have prevented Janet Adams's injury.

The Court finds that further amendment is not warranted. In its prior memorandum, the Court warned the Adamses that "to sufficiently plead negligence and strict-liability theories for design defect," they must "identify economically and technologically feasible alternative EEA stapler designs that do not cut the patient without firing the staples." (Dkt. #24 at 8). The Adamses' conclusory allegations that the O-ring design would be "simple, inexpensive, available, and easily instituted" do not suffice. (Dkt. #68 at 5). Moreover, this case has been pending since November 2019, and the Adamses have already had three chances to plead a viable design defect claim. Finally, the Adamses did not seek leave to amend before the Magistrate Judge issued the Report; instead, they waited until they filed objections to the Report to request leave to amend.

Because amendment would be futile, the Adamses have failed to cure their pleading deficiencies with two prior amendments, the Adamses were dilatory in seeking leave to amend, and permitting amendment would cause undue delay, the Court denies the Adamses' request for leave to amend. *See Jones v. Robinson Prop. Grp.*, 427 F.3d 987, 994 (5th Cir. 2005); *see also Eckels v. Johnson*, 235 F.3d 1340, 2000 WL 1672789, at *1 (5th Cir. Oct. 17, 2000) (unpublished table decision) (per curiam) ("The district court did not abuse its discretion in denying Eckels' request to amend his complaint because Eckels had previously amended his complaint, he did

not make this request until after the magistrate judge had issued his report and recommendation, and, most importantly, he proffered only conclusional allegations in support of his request to amend and did not establish a factual basis for an amendment.").

B. Exemplary Damages

Covidien did not object to the Report's recommendation that the motion to dismiss be denied as to the request for exemplary damages. As such, the Court reviewed this portion of the Report for plain error. Finding none, the Court is of the opinion that the findings and conclusions of the Magistrate Judge are correct and adopts them as the findings and conclusions of the Court.

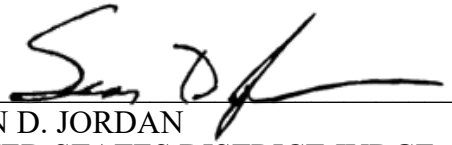
III. CONCLUSION

Based on the foregoing, the Court finds that the Adamses' Objections, (Dkt. #68), are **OVERRULED**.

Covidien's Motion to Dismiss Count I of Plaintiffs' Second Amended Complaint, (Dkt. #26), is hereby **GRANTED in part** and **DENIED in part**.

IT IS ORDERED that the Adamses' design defect claim is **DISMISSED WITH PREJUDICE**. The Court denies the motion to dismiss the Adamses' request for exemplary damages.

So ORDERED and SIGNED this 30th day of March, 2022.



SEAN D. JORDAN
UNITED STATES DISTRICT JUDGE